

REMARKS

The Examiner objected to the language used in the Abstract of the Disclosure. Applicant agrees that the Examiner's recommendation to clarify the meaning is appropriate and thus, Applicant has amended the Abstract accordingly.

REJECTION UNDER 35 U.S.C. §112, First Paragraph

The Examiner rejected claims 1, 2, 5 and 6 under 35 U.S.C. §112, first paragraph, because the specification while enabling for the treatment of migraine disorders, does not provide enablement for the broad functional recitation of "disorders responsive to opening of the KCNQ potassium channels". Applicants believe that one skilled in the art is not unnecessarily burdened with "painstaking experimentation". However, in the interest of advancing prosecution, Applicants have amended claims 1, 2, 5 and 6 to comply with the Examiner's request.

REJECTION UNDER 35 U.S.C. §112, Second Paragraph

Claims 3 and 4 were rejected under 35 U.S.C. §112, second paragraph, by the Examiner. This rejection is now moot since the instant claims 3 and 4 have been cancelled.

Claims 2, 4 and 6 were also rejected by the Examiner as being indefinite in that there is no antecedent basis for certain R definitions in claim 1. Applicants believe that a clerical or word processing error occurred because present claim 1 should be numbered claim 2 and the presently rejected claim 2 should have been numbered claim 1. If this error had not occurred, then none of the limitations exemplified by the Examiner would have occurred. To correct this ambiguity, Applicants have corrected claim 2 and made it into an independent claim.

REJECTION UNDER 35 U.S.C. §103(a)

The Examiner rejected claims 5 and 6 under 35 U.S.C. §103(a) as being unpatentable over *Bos et al.*, of U.S. Patent 6,274,588, because *Bos et al.* teach pharmaceutical compositions of 4-phenyl-pyrimidine derivatives of formula I. The Examiner then concludes that the derivatives of formula I, generically known as 1,3-diazinyl compounds, are known to be useful in treating headaches, especially migraines (column 1, lines 29 and 30).

Applicants respectfully strongly disagree that U.S. Patent 6,274,588 constitutes a *prima facie* obviousness determination that one of ordinary skill in the art would be motivated to utilize these known compounds of *Bos et al.* in "any" pharmaceutical composition. Applicants wish to direct the Examiner's attention to (1) the compounds of formula I are not the same as the compounds of the present invention; (2) the compounds of formula I are antagonists of the Neurokinin 1 (NK-1, substance P) receptor; (3) the compounds of formula I are useful for treating depression, anxiety and psychosis as claimed in claim 11 (column 50); (4) the preferred indications for the cited U.S. Patent are defined in column 3, lines 32-40 and clearly mentions indications only for the treatment of "depressive disorders or emesis"; and (5) the reference to "headaches and especially migraine" is found only in the Background of the Invention and is part of a long list of desired, but not yet proven utilities for antagonists of NK-1 (substance P) receptors which are reviewed in an article, "J. Auton, Pharmacol. 1993". Applicants respectfully submit that there is no connection in the scope and contents of U.S. Patent 6,274,588 with the instant invention. The cited reference of *Bos et al.* does not provide any link to the compounds of the present invention.

The Examiner also rejected claims 5 and 6 under 35 U.S.C. §103(a) as being unpatentable over *Suto et al.*, of U.S. Patent 5,811,428, because one of ordinary skill in the art would have been motivated to utilize these know compounds of *Suto et al.* in "any pharmaceutical composition".

Applicants respectfully disagree and would like to clarify that amended claims 5 and 6 do not claim "any" pharmaceutical composition which would in itself be considered indefinite. Instead, Applicants instant claims are directed to a pharmaceutical composition for the "treatment of migraine". This new use is not suggested by *Suto et al.* since *Suto et al.* provides the compounds to treat inflammatory conditions and only inflammatory related disorders in which the compounds block activation of transcription factors (TFs).

Applicants do not know which element or "piece of the puzzle" was used to arrive at the conclusion that the instant compounds would be useful for the treatment of migraine in a pharmaceutical composition. It is only in the light of Applicants' own application that the desirability of the compounds of the instant invention for the new use becomes apparent.

In view of the foregoing amendments and remarks, Applicants believe that the rejections have been traversed and favorable action on the amended claims is respectfully solicited.

Respectfully submitted,

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